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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/486,266 | 05/03/2000 | THOMAS HILLE | FLA-0035 | 3529 |

7590 04/23/2002

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| EXAMINER |
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GHALI, ISIS A D

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 04/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,266

Applicant(s)

HILLE ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-33, 35-39, 41-49, 53-55 and 57-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33, 35-39, 41-49, 53-55, 57-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' amendment C and drawings correction, both filed 2/12/2002.

Claims 52 and 56 have been canceled and claims 67 and 68 have been added.

Claims 22-33, 35-39, 41-49, 53-55, 57-68 are pending in the application.

Response to Arguments

1. Applicant's arguments filed 2/12/2002 have been fully considered but they are not persuasive.

A. The standing rejection in the application is:

Claims 22-33, 35-39, 41-49, 53-55, and 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 4,390,520 ('520), or US 5,225,199 ('199) each by itself or in combination.

US '520 discloses a transdermal analgesic adhesive comprising a pressure sensitive adhesive layer containing the drug and a flexible substrate (backing). The backing expands on one direction and prepared from polyethylene and having a

moisture permeability from 5 to 2000 g/m²/hr. The adhesive layer comprises vinyl pyrrolidone (abstract; col.2, lines 49-68; col.3, lines 1-2, 55-56).

US '199 teaches a pharmaceutical plaster comprising film layer (represents the backing), adhesive layer containing the drug such as hormone or buprenorphine, and another covering layer removed before use. The film layer has elongation (elasticity) of 30 to 150 % and made of polyethylene terephthalate (abstract; col.3, lines 58-61; col.5, lines 34-35).

No superior and unexpected results were established showing the criticality of the claimed ranges of wrap thread and weft thread. It is within the skill in the art to have differentiated marking elements.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver transdermal therapeutic system comprising adhesive reservoir layer containing the active ingredient; a release liner; and a uni-directional elastic backing disclosed by US '520 and adjusting the elasticity of the backing to that percentage disclosed by US '199, motivated by the teaching of US '520 and US '199 that the elasticity of the backing prevents the sense of tension from the skin, with reasonable expectation of success of delivering a comfortable patch.

B. Applicants argue that:

- US '199 teaches a plaster comprising film layer with an elongation of 30 to 150% in two directions and an additional backing sheet laminated through adhesive to

the film layer, thus, the backing layer and the film layer are two singular, individual and distinct layers. No disclosure in US '199 that the backing layer being unidirectional elastic material having elasticity of at least 20%.

- Regarding US '520, applicants admit that the reference teaches flexible and elastic backing, but argue that the wording "expanding in at least one direction" is not clear and ambiguous description of a unidirectional elastic material having elasticity of at least 20%.
- No motivation or suggestion in the references for combination.
- The teachings of US '199 and US '520 separately or in combination address a problem different from the present invention which is being pleasant for use during long time and minimizing curling effect during manufacture.

C. In response to the above argument, the examiner position is:

- US '199 teaches the film layer that stay on patient skin, along with the drug-containing layer, i.e. the film layer is actually the backing layer and performs the function and made from the same material as applicant's backing layer, but it is named differently. The film layer represents the backing layer. The backing sheet of the reference is a protective layer that is used for leaving the film layer and the drug-containing adhesive on the human skin by applying the plaster and then removing the sheet therefrom (col.7, lines 54-56). Some embodiments of the references do not even have the backing layer, only the film layer (figure 2 and

example 4). The elasticity claimed by the applicants is more than 20%, and the reference disclosed from 30-150%, i.e. that reference meets the claimed ratio. It is within the skill in the art to determine the unidirectional elasticity depending on the required stretchability of the backing layer or motivated by the teaching of US '520 that the backing can have only elasticity in one direction. Note that the "comprising" claims language permits the presence of other layers.

- US '520 clearly teaches that the backing layer expands only in one direction and determining the ratio of the elasticity is within the skill in the art or is taught by US '199 to be between 30-150%.
- In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US '199 suggests the amount of elasticity and US '520 suggests the unidirectional elasticity. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a transdermal therapeutic system comprising a unidirectional elastic backing as disclosed by US '520 and adjusting the elasticity of the backing to that percentage disclosed

by US '199, motivated by the teaching of US '520 and US '199 that the elasticity of the backing prevents the sense of tension from the skin, with reasonable expectation of success of delivering a comfortable patch.

- In response to applicant's argument that the references address problems different from the present invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In any event, the references teach the properties desired by applicants. US '199 teaches that the film layer having an elasticity from 30-150% provides no breakage and no peeling from the skin because of its satisfactory stretchability that is enough to follow skin contraction and expansion (col.2, lines 25-28). The reference, furthermore, discloses that the elasticity between 30-150% provides the best handability and less damage to the plaster on application (col.4, lines 44-48). US '520 teaches that the elastic backing follows the expansion and contraction of the skin when applied to the body (col.3, lines 4-6). Therefore, the cited references provide the features desired by applicants, which are comfortability and less curling during manipulation.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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